

# **Principles in Chemical legislation**

**what the graduate should know**

- *regulations and responsibilities*
- *basic obligations of producers, importers, distributors and downstream users*
- *sources of information*
  - ✓ *Safety data sheet*
  - ✓ *European Chemical Agency (ECHA)*  
<https://echa.europa.eu>

# EU and SK Regulations

Initially (from 1967):

EU Directives (*still valid until 31.5.2017*):

**D**angerous **S**ubstances **D**irective and  
**D**angerous **P**reparations **D**irective

*were 2001 implemented to the national legislation:*

SK Law No.163/2001 ammended in 2010 to the

Law **No. 67/2010** on chemical substances and mixtures  
(references on EU Regulations)

Today (from 2006):

**REACH** Regulation (production/import)

**CLP** Regulation (classification, labeling and packaging and  
placing on the market)

# CLP

Regulation No. **1272/2008** of the EP and of the Council  
on **classification, labelling and packaging** of substances and mixtures,  
amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending  
Regulation (EC) No 1907/2006

## Annexes:

**Annex I:** classification and labeling criteria

**Annex II:** special rules for labelling and packaging of certain substances and mixtures

**Annex III, IV, V:** label elements

**Annex VI:** harmonized classification

**Annex VII:** translation table

## Ammendements:

Commission Regulation No. **790/2009**

Commission Regulation No. **286/2011**

Commission Regulation No. **618/2012**

Commission Regulation No.. **487/2013**

Commission Regulation No.. **758/2013**

Commission Regulation No. **944/2013**

Commission Regulation No.. **605/2014**

Commission Regulation No.. **1297/2014**

Commission Regulation No. **2015/1221**

Commission Regulation No. **2016/918** (valid from 1.2.2018 )

Commission Regulation No. **2016/1179** (valid from 1.3.2018)

**Last consolidated version published by ECHA on 1.1.2017 on :**

<https://echa.europa.eu/regulations/clp/legislation>

# REACH

Regulation No. **1906/2006** of the EP and of the Council  
concerning the

## **Registration, Evaluation, Authorisation and Restriction of Chemicals**

(REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

### ***Large number of ammendements***

*ammendements to the:*

*Annex IV and V (exemtions from registration)*

*Annex XIV (authorisation list – initially empty)*

*Annex XVII (restriction list)*

***consolidated version published by ECHA :***

***<https://echa.europa.eu/regulations/reach/legislation>***

# Inventories

## Outcome of inventarisation of substances in EU (1981)

European **IN**ventory of **EX**isting **CH**emical **S**ubstances - substances on EU market, existing/old substances (*phase in*)

**EC: 2xx-xxx-x** and **3xx-xxx-x**

European **L**ist of **NO**tified **CH**emical **S**ubstances – notified/new substances (*non-phase in*)

**EC: 4xx-xxx-x**

**NLP** – no longer polymers(*phase in*)

**NLP: 5xx-xxx-x**

**List numbers** - *EC numbers automatically assigned by ECHA to the substances without EC number*

**EC: 6xx-xxx-x, 7xx-xxx-x, 9xx-xxx-x**

**SK EINECS** on <http://www.mhsr.sk/10615-menu/142497s>

**CAS** – *Chemical abstract service number*

## **C&L inventory** - **binding classification**

- ✓ *Inventory of substances with harmonized classification (Annex VI of reg. No. 1272/2008)*
- ✓ *Inventory of substances with notified classification (CLP notification according to Articles 39 and 40 of reg. No. 1272/2008)*

# Definitions

**Substance:** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition(> 80% of main component)

**Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community

**Import:** means the physical introduction into the customs territory of the Community

**Importer:** means any natural or legal person established within the Community who is responsible for import

**Downstream user:** means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.

**Article:** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

# Transition periodes

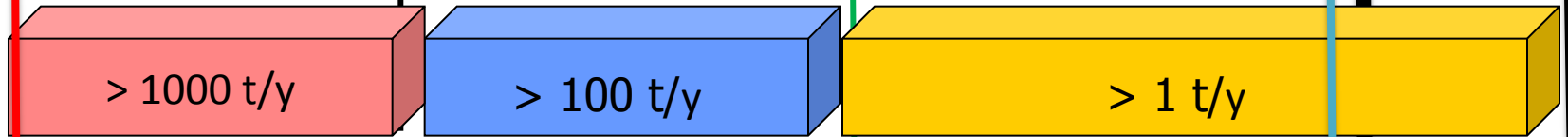
2006

1. June 2008

*pre-registration*

1. June 2017

REACH



1. Dec. 2010

1. June 2013

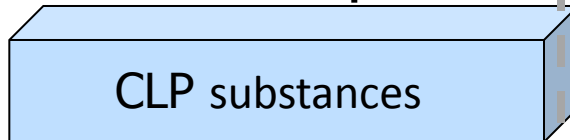
> 1 t/y

*registration*

1. June 2018

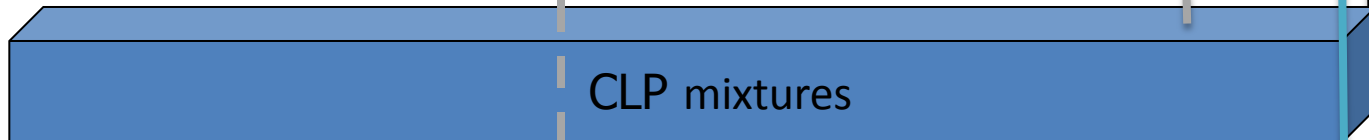
CLP

2008



1. June 2015

1. Dec. 2012



1. June 2017

*Changes in classification*



# Main principles of REACH

**No data, no market**

## Duties of manufacturers and importers of chemicals

### Registration of chemical substances:

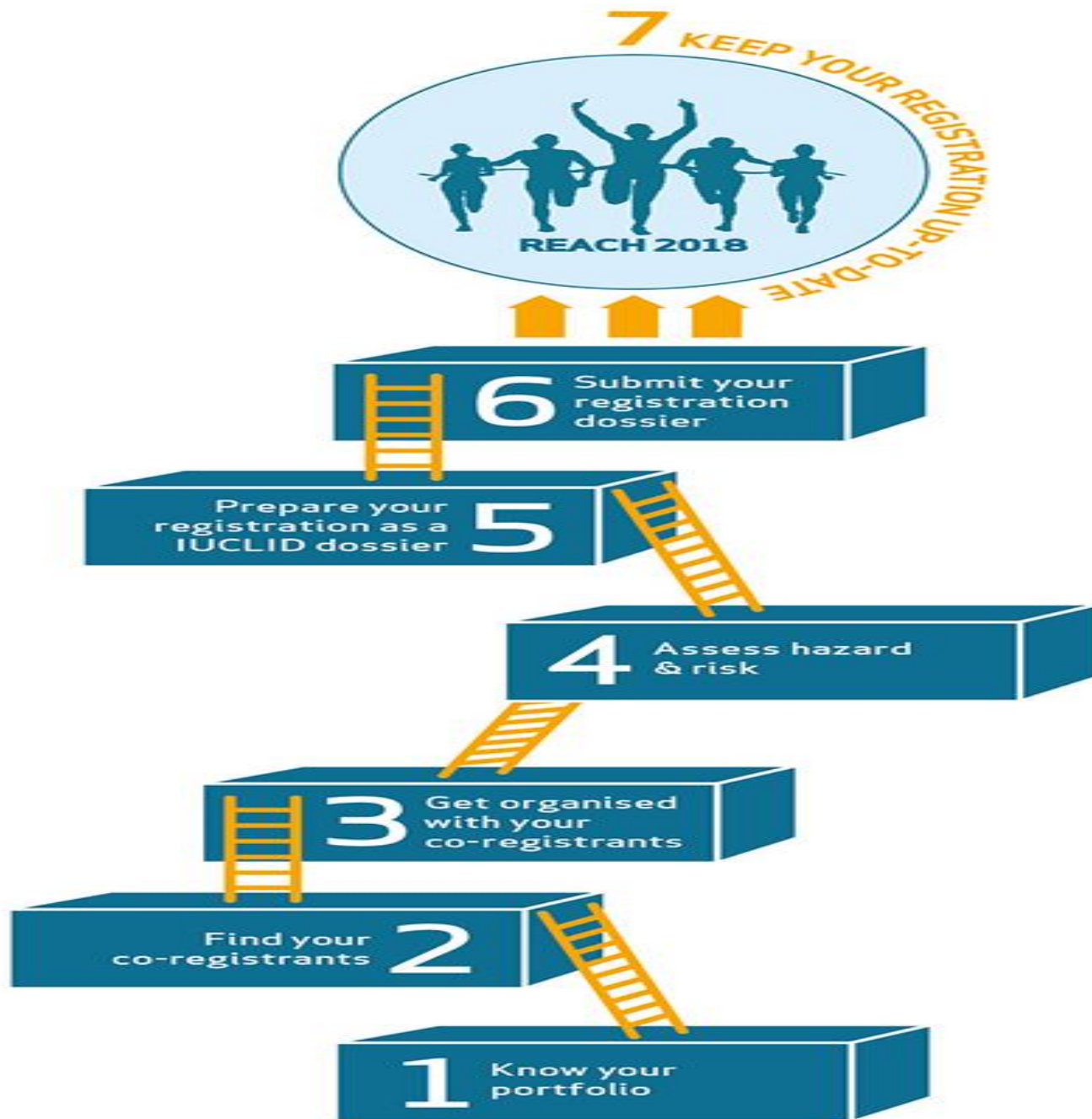
- ✓ > 1t/year
- ✓ **phase in** substances
- ✓ **pre-registration** - *benefit from „transition periodes (until 31.5.2017)*
- ✓ **exemptions** from registration possible
- ✓ **Joint submission** – *Substance Information Exchange Forum*

### Authorisation of chemical substances:

- ✓ **Candidate list** – list of **S**ubstances of **V**ery **H**igh **C**oncern
- ✓ **Authorisation list** (sunset date, review period)

## Duties of manufacturers and importers and Downstream users

- ✓ **Information in supply chain** (*Safety Data Sheet and Exposition Scenario*)
- ✓ **Communication** in supply chain (*up and down*)



# Main principles of CLP

1. **classification and labelling** requirements for hazardous substances and mixtures
2. **label elements:**  
hazard **pictograms**



signal words: **Warning/Danger**

Hazard statements: **2 physical hazard**

**3 human hazard**

**4 environmental hazard**

Precautionary statements: **1 general**

**2 prevention**

**3 Response**

**4 storage**

**5 disposal**

3. **Harmonized classification** (Annex VI)

Table 3.1

č. indexu	Medzinárodná identifikácia látok	č. v ES	č. CAS	Klasifikácia		Označovanie			Špecifické koncentračné hrubý, M-faktory	Poznámky
				Kódy tried a kategórií nebezpečnosti	Kódy výstražných upozornení	Kódy piktogramov a výstražných slov	Kódy výstražných upozornení	Kódy ďalších výstražných upozornení		
601 021 00 3	toluene	203 625 9	108 88 3	Flam. Liq. 2 Repr. 2 Asp. Tox. 1 STOT Rep. 2 (*) Skin Irrit. 2 STOT Single 3	H225 H361d (***) H304 H373 (**) H315 H336	GHS02 GHS08 GHS07 Dgr	H225 H361d (***) H304 H373 (**) H315 H336			
601 022 00 9	o xylene: [1] p xylene: [2] m xylene: [3] xylene [4]	202 422 2 [1] 203 396 5 [2] 203 576 3 [3] 215 535 7 [4]	95 47 6 [1] 106 42 3 [2] 108 38 3 [3] 1330 20 7 [4]	Flam. Liq. 3 Acute Tox. 4 (*) Acute Tox. 4 (*) Skin Irrit. 2	H226 H332 H312 H315	GHS02 GHS07 Wng	H226 H332 H312 H315	(*)		C

Table 3.2

601 021 00 3	toluene	203 625 9	108 88 3	F; R11 Repr. Cat. 3; R63 Xn; R48/20 65 Xi; R38 R67	F; Xn R: 11 38 48/20 63 65 67 S: (2)36/37 46 62				
601 022 00 9	o xylene: [1] p xylene: [2] m xylene: [3] xylene [4]	202 422 2 [1] 203 396 5 [2] 203 576 3 [3] 215 535 7 [4]	95 47 6 [1] 106 42 3 [2] 108 38 3 [3] 1330 20 7 [4]	R10 Xn; R20/21 Xi; R38	Xn R: 10 20/21 38 S: (2)25	Xn; R20/21: C ≥ 12,5 %			C

# *Sources of information*

# Safety data sheet:

## Information from manufacturer/importer down the supply chain

(16 sections containing important data on):

- **identified use** of substance (*section 1*)
- **registration** of substance (*section 1*)
- **classification and labeling** of product (substance or mixture) (*section 2*)
- **hazardous components** of substance or *mixture* (*section 3*)
- **workers exposure** (*section 8*)
- **physical - chemical properties** (*section 9*)
- **toxicological properties** (*section 11*)
- **ecotoxicological key properties** (*section 12*)
- other recommendations for **safe use** (*section 4,5,6,7,8,10*)
- **SVHC** substances/substances for authorisation (*section 15*)
- **restrictions** on the manufacture, placing on the market and use (*section 15*)

# REACH: TITLE XII: INFORMATION

## **Article 119:** *Electronic public access*

1. *The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the internet :*

- (a) the name in the IUPAC Nomenclature, for dangerous substances ..*
- (b) if applicable, the name of the substance as given in EINECS;*

- *information from registration dossiers*
- *information on CLP*
- *other information (biocides, PIC procedure)*
- *scientific information*

<https://echa.europa.eu>

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23/03/2017 - Press release  
**Data on 15 000 chemicals now available to use**



Key information on around 15 000 chemicals can now be downloaded and used. Researchers, regulatory authorities and businesses can use it – not least to improve the safe use of chemicals, enable innovation and help avoid the unnecessary testing of chemicals on animals.

Certain substance tables will be unavailable due to maintenance from Wednesday 5 April 18:00 to Friday 7 April 09:00 (Helsinki time).



[More information >](#)

ECHA apologises for any inconvenience caused.

**News**

03/04/2017 - News item  
**Forum elects new chairs and starts to work with BPR subgroup**

The Forum has elected its new chairs and the Forum's BPR subgroup met for the first time to decide on a project on the control of classification and labelling of biocidal products.

28/03/2017 - News alert  
**Registrants should get ready to comment on 2016 substance evaluation draft decisions**

ECHA will soon send information requests on 27 substances to registrants for comments. These substances were evaluated by the Member States in 2016.

21/03/2017 - News alert  
**Member States to evaluate 22 substances in 2017**

ECHA has adopted the updated Community rolling action plan (CoRAP) which starts the evaluation for the 22 substances listed for 2017. Registrants of the listed substances are encouraged to coordinate their actions and contact the evaluating Member States.

21/03/2017 - News alert  
**Restriction proposal on four phthalates and several authorisation applications agreed by RAC and SEAC**

The Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) agreed on a restriction proposal on four phthalates (DEHP, DBP, DIBP and BBP) in articles and on TDFAs in sprays used by the general public. The committees also agreed on 19 draft opinions and adopted three final opinions on applications for authorisation.

15/03/2017 - News item  
**onised classification and labelling**

**Search for Chemicals** [Advanced search](#)

  
 I have read and I accept the legal notice

**REACH 2018**

**Stakeholders' Day**  
4-9 April 2017, Helsinki, Finland

- REACH-IT
- IUCLID 6
- CHESAR
- R4BP 3
- SPC Editor
- ePIC



# Search for chemicals

echa.europa.eu/search-for-chemicals

An agency of the European Union

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ECHA > Search for Chemicals

Search for Chemicals

Advanced search

50-00-0

Search by name, EC number or CAS Registry number

Name	EC / List no.	CAS no.	
Formaldehyde	200-001-8	50-00-0, 500-00-0	

Showing 1 result.

Export search results to:

**About Us**

- Who we are
- The way we work
- Partners and networks
- Jobs
- Procurement

**Regulations**

- REACH
- CLP
- Biocidal Products Regulation
- Prior Informed Consent Regulation
- Enforcement
- Appeals

**Addressing Chemicals of Concern**

- Substances of potential concern
- Registry of Intentions
- Authorisation
- Restriction
- Harmonised classification and labelling

**Information on Chemicals**

- Registered substances
- Annex III inventory
- Pre-registered substances
- EC Inventory
- Dossier Evaluation decisions

**Chemicals in our Life**

- CLP Pictograms
- What about animal testing?
- Use chemicals safely at work
- Which chemicals are of concern?
- Are there safer alternatives?

**Support**

- Guidance
- Getting started
- Q&As Support
- Testing methods and alternatives
- Webinars
- Dossier Submission Tools

## Substance information

Infocards are automatically generated based on industry data. What is an infocard?

RSS

### Formaldehyde

[Other names: Regulatory process names [2] Trade names [53] IUPAC names [6]

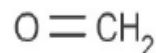


#### Substance identity

EC / List no.: 200-001-8

CAS no.: 50-00-0, 500-00-0

Mol. formula: CH<sub>2</sub>O



#### Hazard classification & labelling



**Danger!** According to the **harmonised classification and labelling** (ATP06) approved by the European Union, this substance is toxic if swallowed, is toxic in contact with skin, causes severe skin burns and eye damage, is toxic if inhaled, may cause cancer, is suspected of causing genetic defects and may cause an allergic skin reaction.

**Additionally**, the classification provided by companies to ECHA in **REACH registrations** identifies that this substance is fatal if inhaled, causes damage to organs, causes serious eye damage and is suspected of causing cancer.

#### About this substance

This substance is manufactured and/or imported in the European Economic Area in 1 000 000+ tonnes per year.

This substance is used in the following products: adhesives and sealants, polymers, laboratory chemicals and coating products. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging and building & construction work. This substance is used for the manufacture of: chemicals, plastic products, textile, leather or fur, pulp, paper and paper products, mineral products (e.g. plasters, cement) and rubber products.

Release to the environment of this substance is likely to occur from industrial use: formulation of mixtures, formulation in materials, in the production of articles and as processing aid. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners).

This substance can be found in complex articles, with no release intended: machinery, mechanical appliances, electrical/electronic products not covered by Waste Electrical and Electronic Equipment (WEEE) directive (e.g. large-scale stationary industrial tools). This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones) and wood (e.g. floors, furniture, toys).

#### Properties of concern



#### Important to know

- Substance included in the Community Rolling Action Plan (CoRAP).

#### How to use it safely

- ECHA has no data from registration dossiers on the precautionary measures for using this substance.
- Guidance on the safe use of the substance provided by manufacturers and importers of this substance.

about INFOCARD - Last updated: 24/03/2017

# Regulatory activities

echa.europa.eu/substance-information/-/substanceinfo/100013751

with material based on: stone, plaster, cement, glass or ceramic (e.g. dishes, pots/pans, food storage containers, construction and isolation material), fabrics, textiles and apparel (e.g. clothing, mattress, curtains or carpets, textile toys), rubber (e.g. tyres, shoes, toys), metal (e.g. cutlery, pots, toys, jewellery), leather (e.g. gloves, shoes, purses, furniture), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper) and wood (e.g. floors, furniture, toys).

Alert INPCARD - Last updated: 15/03/2017

## Regulations and regulatory activities

This substance has been found in the following regulatory activities:

### BPR

- Biocidal Active Substances
- Biocidal Authorised products

### CLP

- CSL Inventory
- Registry of withdrawn Harmonised Classification and Labeling intentions and submissions

### ESR

- EC Inventory

### REACH

- Agreements of the MSC on Identification of Substances of Very High Concern
- Candidate List
- Identification of Substances of Very High Concern - previous consultation
- Pre-registration process
- Recommendation for inclusion in the authorisation list - previous consultation
- Registration dossier
- Registry of submitted SVHC intentions
- Substances in Articles

## Other names

### Regulatory process names

- Boric oxide
- Diboron trioxide
- Diboron trioxide

### Trade names

- ANHYDROUS BORIC ACID
- boric oxide

# Brief profile

echa.europa.eu/brief-profile/-/briefprofile/100.000.002

## Formaldehyde

Substance description

Scientific properties

Brief Profile - Last updated: 24/03/2017 [Print](#)

### Physical and chemical properties

This section provides physicochemical information compiled from all automatically processable data from REACH registration dossiers that is available to ECHA at the time of generation. The quality and correctness of the information remains the responsibility of the data submitter. The Agency thus cannot guarantee the correctness of the information displayed.

### Physical and chemical properties

- Appearance/physical state / colour
- Melting/freezing point
- Boiling point
- Density
- Vapour pressure
- Partition coefficient
- Water solubility
- Solubility in organic solvents / fat solubility
- Surface tension
- Flash point
- Auto flammability
- Flammability
- Explosiveness
- Oxidising
- Oxidation reduction potential
- pH
- Dissociation constant
- Viscosity

### Appearance/physical state / colour

#### Study results

17 studies submitted  
17 studies processed

#### Physical state at 20°C and 1013 hPa

Gaseous (71%), Liquid (29%) [17]

#### Form

Other (100%) [1]

#### Odour

Pungent (67%), Other (33%) [15]

#### Substance type

Organic (100%) [9]

#### Type of Study provided

##### Studies with data

	▲	□	■	▲
Key study				
Supporting study				
Weight of evidence	1			16
Other				

##### Data waiving

no waivers

#### Summaries

0 summaries submitted  
0 summaries processed

▲ No data available.

### Melting/freezing point

#### Study results

18 studies submitted  
16 studies processed

#### Melting / freezing point

-118.3 - -9 °C @ 101.3 - 101.325 kPa [18]

#### Type of Study provided

##### Studies with data

	▲	□	■	▲
Key study	1			
Supporting study	2			
Weight of evidence				15
Other				

##### Data waiving

no waivers

#### Summaries

0 summaries submitted  
0 summaries processed

▲ No data available.

### Boiling point

# CLP – harmonised classification


## Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

### General Information

Index Number	EC Number	CAS Number	International Chemical Identification
649-224-00-6	269-822-7	68334-30-5	<p>Fuels, diesel</p> <p>Gasoil - unspecified</p> <p>[A complex combination of hydrocarbons produced by the distillation of crude oil. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C20 and boiling in the range of approximately 163 oC to 357 oC (325 oF to 675 oF).]</p>

ATP Inserted / Updated: CLP00 ⓘ  
 CLP Classification (Table 3.1)

Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Carc. 2	H351	H351		GHS08 Wng		Note N


Signal Words	Pictograms
Warning	 Health hazard



ECHA support: <https://echa.europa.eu/sk/support/guidance>

echa.europa.eu/support

About Us Regulations Addressing Chemicals of Concern Information on Chemicals Chemicals in our Life Support

ECHA > Support  123

## Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

### REACH

- Guidance documents
- Manuals
- Identify your obligations
- Practical examples of exposure scenarios
- Testing methods and alternatives
- Downstream user report
- How to improve your dossier
- Registration
- Substance identification
- Restriction
- Authorisation
- Socio-economic analysis in REACH
- Small and Medium Enterprises

Getting started with EU chemicals legislation

Publications

Helpdesks

Q&As Support  
Webinars

Croatian accession

### CLP

- Guidance documents
- Submission of CLH dossiers
- Small and Medium Enterprises
- Mixture classification

### Biocidal Products Regulation

- Guidance documents
- Emission scenario documents
- R4BP 3
- Small and Medium Enterprises

### Dossier Submission Tools

- REACH-IT
- IUCLID
- CHESAR
- R4BP 3
- SPC Editor tool
- ePIC

*Thank you for your attention*